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Dockets Management Branch (HFA-305)
Food and Drug Administration
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MERCK
Research Laboratories

RE: [Docket Nos. 03D-0060, 99D-1458, 00D-1538, 00D-1543, 00D-1542, and 00D-1539] *Draft Guidance for Industry* on "Part 11, Electronic Records, Electronic Signatures—Scope and Application;" Availability of Draft Guidance and Withdrawal of Draft Part 11 Guidance Documents and a Compliance Policy Guide

Merck & Co., Inc. is a leading worldwide human health product company. Through a combination of the best science and state-of-the-art medicine, Merck's research and development (R & D) pipeline has produced many of the important pharmaceutical and biological products on the market today.

At Merck, information management is pivotal in supporting all of our activities from drug discovery, through demonstration of safety and efficacy, and finally through manufacture and distribution to the public. Through our use of information technologies and our experience in maintaining records important to us and to FDA, Merck is well-qualified to comment on this *Draft Guidance for Industry* on "Part 11, Electronic Records, Electronic Signatures—Scope and Application" (hereafter referred to as *The Draft Guidance*).

General Comment

Merck appreciates the opportunity to review *The Draft Guidance* and to share our comments on this important topic. In the past, we have participated in a continuous dialogue with regulators on Part 11 issues and we have attempted to clarify certain requirements for those of us subject to these regulations, as well as to promote reasonable expectations for regulators about what is achievable for regulatory compliance.

Merck applauds FDA's decision to undertake a major re-examination of the 21 CFR Part 11 regulation, in relation to the current Good Manufacturing Practice (cGMP) initiative. During the examination of cGMPs, FDA's willingness to narrowly interpret the scope of Part 11 and to exercise enforcement discretion in the specified areas of legacy systems, validation, audit trails, record retention, and copying of records seems very reasonable. The emerging risk-based approach to ensuring product quality, patient safety and record integrity that will be used for cGMPs should also serve well in interpreting Part 11 requirements.

It is apparent from this document that the FDA has been listening carefully to the comments and concerns of industry, expressed by the individual pharmaceutical companies and by the Industry Coalition on Part 11. We look forward to finalization of *The Draft Guidance* and to revisions to 21 CFR Part 11 regulations, that may be necessary to incorporate changes in perspective defined here and any new concepts that evolve from the cGMP initiative.

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We welcome the opportunity to comment on *The Draft Guidance* and, as appropriate, to meet with you to discuss Part 11 experiences and issues.

Sincerely,

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